



## ***Press Release***

### **Granules India Limited announces approval of Trospium Chloride ER Capsules, 60 mg,**

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**Hyderabad, April 24, 2020**

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc (GPI)., a wholly owned foreign subsidiary of Granules India Limited for Trospium Chloride Extended-Release Capsules, 60 mg. It is bioequivalent to the reference listed drug product (RLD), Sanctura XR Capsules, 60 mg, of Allergan, Inc.

Trospium Chloride Extended-Release Capsules are a muscarinic antagonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

“We are pleased to announce approval of this niche, limited competition product, which is a nice addition to our growing product portfolio in the US market.” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Trospium Chloride Extended-Release Capsules, 60 mg had U.S. sales of approximately \$25 million MAT for the most recent twelve months ending in February 2020 according to IQVIA Health.

Granules now has a total of 26 ANDA approvals from US FDA (24 Final approvals and 2 tentative approvals).



## **About Granules India Ltd. (BSE: 532482, NSE: GRANULES)**

Granules India is a growing pharmaceutical manufacturing company with best in class facilities and is committed to operational excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. The Company has 6 manufacturing facilities out of which 5 are located in India and 1 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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### ***Safe Harbour***

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